5. 510(k) Summary

K071192

JUN 22 2007

LANCER
ORTHODONTICS

Submitter's name:	Lancer Orthodontics
Address:	253 Pawnee Street San Marcos, CA 92078
Phone:	760-744-5585
Fax number:	760-744-5842
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 fax: 949-552-2821

Date the summary was prepared:	April 25, 2007
Name of the device:	Blugoo HD
Trade or proprietary name:	Blugoo HD
Common or usual name:	Dental impression material
Classification name:	Material, Impression

The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

Extrude, manufactured by Sybron Dental Specialties, Inc. The reference number is K012405.

Description of the device:

Blugoo HD is a three part product (Part A, Part B, and Part C). Part A and B are a two part resin based impression mix.

Blugoo HD Part C Yellow Wash is a two part resin based impression material. It can be used in conjunction with Blugoo HD for high definition impressions.

Indications:

Blugoo HD is used to reproduce the structure of a patient's teeth and gums.

Summary of the technological characteristics of our device compared to the predicate device:

Extrude, manufactured by Sybron Dental Specialties, Inc. and Blugoo HD were compared in the following areas and found to have similar technological characteristics and therefore to be equivalent.

Anatomical sites
Design
Formulation
Type
Intended use
Mixing time
Working time
Min removal time from start of mix
Linear dimensional change
Elastic recovery
Strain in compression
Impression longevity
Storage conditions
Detail reproduction
Compatibility with gypsum

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2007

Lancer Orthodontics, Incorporated
C/O Ms. Grace Holland
Regulatory Specialists, Incorporated
3722 Ave. Sausalito
Irvine, California 92606

Re: K071192
Trade/Device Name: Blugoo HD
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: June 14, 2007
Received: June 18, 2007

Dear Ms. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K071192

Device Name: Blugoo HD

Indications For Use:

Blugoo HD is used to reproduce the structure of a patient's teeth and gums.

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...tion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ction Control, Dental Devices

...(k) Number: K071192